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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,894	12/28/2004	Hinrich Wiese	62584(45107)	9848
21874	7590	06/15/2006	EXAMINER	
EDWARDS & ANGELL, LLP			BERNSHTEYN, MICHAEL	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1713	
DATE MAILED: 06/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/519,894

Applicant(s)

WIESE ET AL.

Examiner

Michael Bernshteyn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/28/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to a combination of at least one building material and a bath fluid, classified in class 526, subclass 298;
 - II. Claims 20, 23 and 24, drawn to a method for producing an element, classified in class 700, subclass 119;
 - III. Claim 21, drawn to a method for producing an element, classified in class 700, subclass 119;
 - IV. Claim 22, drawn to a method for producing an element, classified in class 700, subclass 119;
 - V. Claim 25, drawn to an element obtained by a method, classified in class 427, subclass 424;
 - VI. Claim 26, drawn to an element produced from a combination of building material and bath fluid, classified in class 427, subclass 424;
 - VII. Claims 27-29, drawn to a polymer having improved hydrolysis stability, classified in class 526, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and VI, I and VII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP §

806.04(h)). In the instant case, the intermediate product is deemed to be useful as a composition of at least one building material and a bath fluid for a method of directly printing elements and models, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Inventions II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case an element can be obtained using different method, such as rapid phototyping method, etc.

4. Inventions of I+II, I+III, I+IV, I+V, II+III, II+IV, II+VI, II+VII, III+IV, III+V, III+VI, III+VII, IV+V, IV+VI, IV+VII, V+VI, V+VII, and VI+VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a combination, three methods for producing an element, an element and a polymer having improved hydrolysis stability,

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are completely different inventions because they have different functions and different effect.

5. Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reason given above and the search required for Group I is not required for Groups II-VII, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Ms. Christine C. O'Day (Registration No. 38,256) on May 5, 2006 a provisional election was made **without traverse** to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this office action. Claims 20-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Claims 1-19 are active in the Application.

Claim Objections

9. Claim 7 is objected to because of the following informalities: improper Markush group format. According MPEP § 2171.05(h), one acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected **from the group consisting of A, B and C.**" See ***Ex parte Markush***, 1925 C.D. 126 (Comm'r Pat. 1925). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (U. S. Patent 6,306,243) in view of Ederer et al. (WO 01/26885 A1).

Clark discloses the pH-modified monomer and polymer compositions are useful as biomedical and surgical adhesives, sealants, implants and bioactive agent release carriers or matrices (abstract).

With regard to the limitation of the claim 1, Clark discloses that typically, when used as adhesives and sealants, cyanoacrylates are applied in monomeric form to the surfaces to be joined or sealed, where, typically, in situ anionic polymerization of the monomer occurs, giving rise to the desired adhesive bond or seal. Implants, such as rods, meshes, screws, and plates, may also be formed of cyanoacrylate polymers, formed typically by radical-initiated polymerization (col. 1, lines 41-48).

Preferred monomers are cyanoacrylates having the formula



In the cyanoacrylate monomer of formula (II), R² is hydrogen, R³ is preferably an alkyl group having 1-10 carbon atoms or a group having the formula -AOR⁹, wherein A is a divalent straight or branched chain alkylene or oxyalkylene radical having 2-8 carbon atoms, and R⁹ is a straight or branched alkyl radical having 1-8 carbon atoms.

Polymerization of the monomer mixture is accelerated with **aqueous solution** (Examples 1-3, 5, 9-18, 1C-3C, 5C, and 9C-18C, col. 12, line 15).

With regard to building material contains at least one low-viscosity monomeric or oligomeric compound having a viscosity < 200 mPa.s, instantly claimed in claim 1, Clark

is silent about it. However, in view of substantially identical composition between Clark and instant claims, it is the examiner position that Clark's composition possesses this property. Since the USPTO does not have equipment to do the analytical test, the burden is now shifted to the applicant to prove otherwise.

Clark does not disclose a combination of at least one building material and a bath fluid for a method for directly printing elements and models.

Ederer discloses a combination of a building material and a bath fluid (supporting fluid) for a method for directly printing components and models, the building material being a liquid resin that is solidified by reaction with a reaction agent contained in the bath fluid (page 11, line 33 through page 12, line 1). The bath liquid consists of an aqueous solution (page 11, lines 20-33). This method is substantially identical to the method for directly printing visual-aid models or elements, described in the specification (see the specification, page 2 line 22 through page 4 line 20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the combination of at least one building material and a bath fluid for a method for directly printing elements and models as taught by Ederer, in Clark's improved polymer composition, because in that case it is not necessary to use solidified supporting materials for having a supporting surface onto which the building material of the subsequent layer for forming the projecting or cantilevering portions can be deposited (WO'885, page 3, lines 28-33).

With regard to the limitation of the claim 2, Clark discloses that pH modifier may include many additives (col. 6, lines 35-36).

With regard to the limitation of the claim 3, Clark discloses that especially advantageous cyanoacrylate monomers are **methyl cyanoacrylate, butyl cyanoacrylate, 2-octyl cyanoacrylate, 1-methoxy-2-propyl cyanoacrylate, 2-butoxyethyl cyanoacrylate, 2-isopropoxyethyl cyanoacrylate and 3-methoxybutyl cyanoacrylate** (col. 4, lines 19-34).

With regard to the limitation of the claims 4-14, Clark discloses that the polymer composition may include, for example, but is not limited to, an **acidic compound** or anhydrous precursor thereof or a chemically protected acid. For example, the pH modifier may comprise at least one member selected from the group consisting of: amino acids; **carboxylic acids and salts thereof**; di-acids and salts thereof; poly-acids and salts thereof; esters that are easily hydrolyzable in vivo; lactones that are easily hydrolyzable in vivo; organic carbonates; enolic compounds; acidic phenols; polyphenolic compounds; aromatic alcohols; ammonium compounds or salts thereof; boron-containing compounds; **sulfonic acids and salts thereof**; sulfinic acids and salts thereof; **phosphorus-containing compounds**; acid halides; chloroformates; acid gases; acid anhydrides; inorganic acids and salts thereof; and polymers having functional groups of at least one of the preceding members. The pH modifier may, for example, comprise at least one member selected from the group consisting of: **glycine**; alanine; proline; **lysine**; glutaric acid; D-galacturonic acid; **succinic acid**; lactic acid; glycolic acid; **poly(acrylic acid)**; sodium acetate; diglycolic anhydride; succinic anhydride; citraconic anhydride; maleic anhydride; lactide; diethyl oxalate; Meldrum's acid; diethyl carbonate; dipropyl carbonate; diethyl pyrocarbonate; diallyl pyrocarbonate;

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di-tert-butyl dicarbonate; ascorbic acid; catechin; ammonium chloride; D-glucosamine hydrochloride; 4-hydroxy-ephedrine hydrochloride; boric acid; nitric acid; hydrochloric acid; sulfuric acid; **ethanesulfonic acid**; and **p-toluenesulfonic acid**; 2-aminoethylphosphoric acid; methylphosphonic acid; dimethylphosphinic acid; methyl chloroformate; **sulfur dioxide**; and carbon dioxide (col. 6, lines 35-65).

Also, the polymer composition may include at least one member selected from the group consisting of: hydroxides; alkoxides; basic carbonates; nitrogen-containing compounds; amines; alkaloids; hydrides; organolithium compounds; Grignard reagents; carbanions; and polymers having functional groups of at least one of the preceding members. The pH modifier (whether single or in combination) may be, for example, selected from the group consisting of **sodium hydroxide**; potassium hydroxide; sodium methoxide; potassium t-butoxide; **sodium carbonate**; calcium carbonate; dibutylamine; tryptamine; sodium hydride; calcium hydride; butyllithium; and ethylmagnesium bromide (col. 7, lines 18-30).

Composition may further contain a stabilizer and/or one or more **adjuvant substances**, such as thickening agents, plasticizers, or the like. Examples of coating materials that can be used include, but are not limited to: **polyesters, such as polyglycolic acid, polylactic acid**, copolymers of polyglycolic acid and polylactic acid, polycaprolactone, polyester hydrogels; polyvinylpyrrolidone; polyamides; gelatin; albumin; proteins; collagen; poly(orthoesters); poly(anhydrides); poly(alkyl-2-cyanoacrylates); poly(dihydropyrans); poly(acetals); poly(phosphazenes); poly(urethanes); poly(dioxinones); **cellulose**; and **starches** (col. 8, lines 39-60).

Suitable thickeners include, for example, **polycyanoacrylates**, polylactic acid, polyglycolic acid, lactic-glycolic acid copolymers, **polyalkyl acrylates**, copolymers of alkylacrylate and vinyl acetate, **polyalkyl methacrylates**, and copolymers of alkyl methacrylates and butadiene (col. 8, line 66 through col. 9, line 5).

With regard to the limitation of the claims 15-17, Clark discloses that to improve the cohesive strength of adhesives formed from the compositions, difunctional monomeric **cross-linking agents** may be added to compositions or used in methods of this invention in vivo or ex vivo. Such **crosslinking agents** are known. Examples of suitable crosslinking agents include alkyl bis(2-cyanoacrylates), triallyl isocyanurates, alkylene diacrylates, alkylene dimethacrylates, trimethylol propane triacrylate, and alkyl bis(2-cyanoacrylates). When used ex vivo, a catalytic amount of a free radical initiator is added to initiate polymerization of the cyanoacrylate monomer/crosslinking agent blend (col. 9 lines 12-25)

With regard to the limitation of the claim 18, Clark discloses that the compositions may further contain fibrous reinforcement and colorants, e.g., **dyes** and **pigments** (col. 9, lines 29-31).

With regard to the limitation of the claim 19, Clark does not disclose the ratio of density between building material (polymer composition) and bath fluid (aqueous solution).

Ederer discloses that it is preferred that in methods using a supporting liquid reservoir, the supporting liquid has a density which is only slightly higher than that of the

building material, preferably 1.01 to 2 times as high, and further preferably 1.05 to 1.5 times as high (page 11, lines 1-5).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the ratio of density between building material (polymer composition) and bath fluid (aqueous solution) in the above range as taught by Ederer using Clark's polymer composition in order to achieve that on the one hand, the building material deposited to the supporting liquid is supported by the latter, but on the other hand, the structural body immersed into the supporting liquid in the receptacle does not experience any essential buoyancy, which cause significant forces to act on the structural body and thus may cause damage to the structural body (WO'885, page 11, lines 6-12).

It is noted that the density ratio is a result effective variable, and therefore, it is within the skill of those skilled in the art to find the optimum value of a result effective variable, as per ***In re Boesch and Slaney*** 205 USPQ 215 (CCPA 1980). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bernshteyn whose telephone number is 571-272-2411. The examiner can normally be reached on M-F 8-5:30.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Bernshteyn
Patent Examiner
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